Office Action Summary

Application No.	Applic...(s)
09/284,555	Croll-Kalish et al.
Examiner	**Group Art Unit**
ANISH GUPTA	1653

☒ Responsive to communication(s) filed on *May 26, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-18* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-18* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Acknowledgment of the preliminary amendment, filed 5-26-99 is made. The amendment amended claims 4-5, 10-11 and 16-17 and canceled claims 19-21. Therefore, claims 1-17 are pending.

Claim Rejections - 35 USC § 101

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

A use, perse is not statutory claim of invention. These claims have been read as if in proper process of use format (applicant is required to properly amend the claims) as the following grounds of rejection under 35 USC 112, 102 and 103.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6 and 12-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims 1-6 and 13-17 state that the compound is useful in the enhancement of the intracerebral, extra cerebral, intrapareenchymal, intracerebraventricular or intrathecal delivery of the growth factor. However, it is unclear what the enhancement is being measured against. The claims do not recite a point of reference that accurately determines the enhancement of the intracerebral, extra cerebral, intrapareenchymal, intracerebraventricular or intrathecal delivery of the growth factor.

Claims 6, 12 and 18 recite TrkBIgG. However, this is incorrect since it should be recited TrkB-IgG.

Claims 1-6 provide for the use of a soluble form of a receptor, but, the claim(s) do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng et al.

The claims are drawn to compositions comprising growth factor(s) and a soluble form of a receptor for said growth factor(s).

The reference formulation of TrkB-IgG that is administered in experimental cultures at the same time as the neurotrophins (see page 5080). The neurotrophins include NGF, BDNF, and NT-3 (see page 5080). The reference specifically states the administration of TrkB-IgG where BDNF has already been administered (see page 5081). Therefore, the reference teaches formulations that contain both BDNF and TrkB-IgG. Although the reference teaches the administration of the components separately, the instant specification allows for the administration of BDNF and TrkB-IgG independently or sequentially (see page 11 of the specification). Thus, the reference anticipates claims drawn to composition comprising growth factor(s) and a soluble form of a receptor for said growth factor(s).

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 7-9 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prisell et al. in view of Sable et al.

The claims are drawn to methods of use of and composition(s) comprising a growth factors and a soluble form of a receptor for said growth factors.

The reference of Prisell et al. teach pharmaceutical formulations comprising Nerve Growth Factor, Nerve Growth factor Receptor, and hyaluronic acid (see claim 1-5). The reference teaches that the pharmaceutical formulation results in a slow release of the biological active peptides (see page 2). The art recognizes that intracerebral administration of Nerve Growth Factor is useful in enhancing the degree of behavioral recovery in brain damaged animals (see col. 2, lines 17-37 in Sable et al.). The difference between the prior art and the instant application is that the reference does not teach the enhancement of the intracerebral, extra cerebral, intrapareenchymal, intracerebraventricular or intrathecal delivery of the growth factor.

However, since NGF is useful for enhancing the degree of behavioral recovery in brain damaged animals, it would have been obvious to administer the composition of Prisell et al. because the slow release of the peptide increases the half life. Moreover, since the treatment of brain damaged animals requires intracerebral administration, a formulation comprising Nerve Growth Factor, Nerve Growth factor Receptor, and hyaluronic acid would necessarily result in an enhancement of the intracerebral delivery of the growth factor. Thus, the combined reference make prima facie obvious the claimed invention of claims drawn to methods of use of and composition(s) comprising a growth factors and a soluble form of a receptor for said growth factors.